

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: Benjamin OSHLACK, et al.
Serial No.: To Be Assigned
Filed: Herewith
For: **MELT-EXTRUDED ORALLY
ADMINISTRABLE OPIOID FORMULATIONS**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

October 21, 2003

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 (18 pages) for consideration by the Examiner in connection with the examination of the above-identified patent application. Pursuant to 37 C.F.R. § 1.98(d), copies of the references listed on pages 1-18 of the Form PTO-1449 are not enclosed because these references have already been considered and made of record in the parent case, U.S. Patent Application Serial No. 09/360,056.

Applicants note that EP0574894 A1, designated as reference numeral RG was cited by the Examiner in a corresponding European patent application. Further, reference numeral RK, is an English translation of a publication in Japanese entitled "*Twin Screw Extrusion, Technology and Principles*" by J.L. White (pages 14 and 37) which was cited in a third party submission to the Japanese Patent Office with regard to the inventive step of the claims of a related Japanese Patent application. (See Communication dated December 26, 2000 submitted in related U.S. Patent application Serial No. 09/360,056).

Applicants further note that in addition to reference RK, the third party submitted 7 other references. These references are listed below as 2-8:

- 2) Japanese Patent Application Laying Open (kokai) No. 5-194197 (U.S. Patent No. 5,552,159 to Mueller et al.);
- 3) Japanese Patent Application Laying Open (kokai) No. 7-53361 (EP 0624366 B1);
- 4) Japanese Patent Application Laying Open (kokai) No. 63-122623 (U.S. Patent No. 4,990,341 to Goldie et al.);
- 5) Japanese Patent Application Laying Open (kokai) No. 2-107260 (U.S. Patent No. 5,073,379 to Klimesch et al.);
- 6) Japanese Patent Application Laying Open (kokai) No. 260029 (AU-A-57224/86);
- 7) WO 94/08568 (U.S. Patent No. 5,700,410 to Nakamichi et al.); and
- 8) WO93/07859.

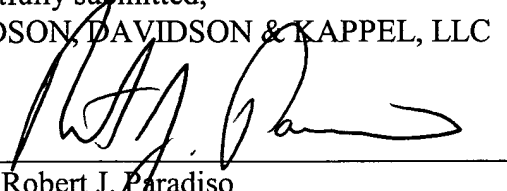
These additional references, 2-8, are included as reference numerals FI, NO, JF, BG, ND, AL, and AO, respectively on the enclosed Form PTO-1449 and have already been considered and made of record in the parent case. Accordingly, copies of these references are not enclosed herewith.

The present Information Disclosure Statement is filed under 37 C.F.R. §1.97(b), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

It is respectfully requested that the reference cited on the accompanying Form PTO-1449 be considered and made of record.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____


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Reg. No. 41,240

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(212) 736-1940

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1030. CON3		SERIAL NO.: To Be Assigned						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Benjamin OSHLACK et al.								
						FILING DATE: Herewith		GROUP: Unknown						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	AA	4	1	3	2	7	5	3	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	4	1	3	2	7	5	3	01/02/79	Blichare et al.	264	25	11/03/67	
	AB	4	5	3	3	5	6	2	08/06/85	Ikegami et al.	427	3	04/19/84	
	AC	4	7	6	4	3	7	8	08/16/88	Keith et al.	424	435	02/10/86	
	AD	4	8	2	8	8	3	6	05/09/89	Elger et al.	424	419	05/19/87	
	AE	4	8	8	2	1	6	7	11/21/89	Jang	424	468	11/24/87	
	AF	4	8	8	0	8	3	0	11/14/89	Rhodes	424	470	02/09/87	
	AG	4	8	9	4	2	3	4	01/16/90	Sharma et al.	424	440	07/26/88	
	AH	4	9	9	4	2	2	7	02/19/91	Dietz et al.	264	328.16	02/03/89	
	AI	5	0	2	3	0	8	9	06/11/91	Sakamoto et al.	424	502	07/13/89	
	AJ	5	0	5	5	3	0	7	10/08/91	Tsuru et al.	424	693	12/28/89	
	AK	5	1	3	3	9	7	4	07/28/92	Paradissis et al.	424	480	01/24/90	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
		WO	94	0	8	5	6	8					YES	NO
	AL	WO	94	0	8	5	6	8	04/28/94	PCT	A61K	9/26		X
	AM	WO	94	2	3	6	9	8	10/27/94	PCT	A61K	9/14	X	
	AN	WO	93	2	4	1	1	0	12/09/93	PCT	A61K	9/20		X
	AO	WO	93	0	7	8	5	9	04/29/93	PCT	A61K	9/16	X	
	AP	0	3	3	7	2	5	6	11/19/92	EPO	A61K	9/20		X
	AQ	0	4	8	1	6	0	0	04/22/92	EPO(A2)	A61L	15/28	X	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AR	Nicolas Follonier ¹ , Eric Doelker and Ewart T. Cole, <u>Evaluation of Hot-Melt Extrusion as a New Technique for the Production of Polymer-Based Pellets for Sustained Release Capsules containing high loadings of freely soluble drugs</u> , Drug Development and Industrial Pharmacy, 20(8), 1323-1339 (1994)												
	AS	Nicolas Follonier ¹ , Eric Doelker ¹ and Ewart T. Cole ² , <u>Hot-Melt Extruded Pellets for the Sustained Release of Highly Dosed Freely Soluble Drugs</u> , Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 18(1991), pages 578-579												
	AT	Twin Screw Extrusion in the Production of Novel Dosage Forms, Pharmaceutical Manufacturing Review (June 1994)												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

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						FILING DATE: Herewith		Group.: Unknown						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	GROUP: 1617		
	BA	5	2	7	3	7	5	8	12/28/93	Royce	424	465	04/13/92	
	BB	5	3	8	0	5	3	5	01/10/95	Geyer et al.	424	484	11/25/92	
	BC	5	2	0	2	1	2	8	04/13/93	Morella et al.	424	469	08/24/90	
	BD	Re.		3	3	0	9	3	10/17/89	Schiraldi et al.	424	676	11/16/88	
	BE	5	3	5	6	6	3	5	10/18/94	Raman et al.	424	484	07/13/93	
	BF	5	1	8	3	6	9	0	02/02/93	Carr et al.	427	213.31	06/25/90	
	BG	5	0	7	3	3	7	9	12/17/91	Klimesch et al.	424	467	08/25/89	
	BH	4	9	5	7	6	8	1	09/18/90	Klimesch et al.	264	211.23	04/03/89	
	BI	5	2	8	3	0	6	5	2/1/94	Doyon, et al.	424	467	3/23/92	
	BJ	4	8	0	6	3	3	7	2/21/89	Snipes, et al.	71	65	10/14/86	
	BK	5	2	9	0	5	6	0	3/1/94	Autant, et al.	424	438	6/21/91	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BL	0	3	5	8	1	0	7	03/14/90	EPO (A2)	A61K	9/20		X
	BM	2	0	8	2	5	7	3	05/24/93	Canada	A61K	047/38	X	
	BN	0	5	8	0	8	6	0	02/02/94	EPO (A1)	A61K	9/14	X	
	BO	0	2	4	0	9	0	4	07/01/92	EP0 (B1)	A61K	9/20		X
	BP	0	2	4	0	9	0	6	10/14/87	EPO (A2)	A61J	3/10		X
	BQ	0	3	3	7	2	5	6	10/18/89	EPO (A2)	A61K	9/20		X
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	BR	Follonier, Nicolas, et al., "Hot-Melt Extruded Pellets For The Sustained Release Of Highly Dosed Freely Soluble Drugs", Capsule News, Vol. 1, No. 3, Edited by Roland Daumesnil, (June/July 1991)												
	BS	Frank W. Goodhart et al., Design and Use of a Laboratory Extruder for Pharmaceutical Granulations, Journal of Pharm. Scien., 62(1), p. 133-136 (January 1973).												
	BT	Publication, KEX, Twin Screw Compounding Extruder, (October 1989).												
EXAMINER										DATE CONSIDERED				
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						FILING DATE: Herewith		GROUP: Unknown						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	CA	5	0	4	9	3	9	4	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	CA	5	0	4	9	3	9	4	9/17/91	Howard, et al.	424	490	3/15/89	
	CB	4	8	6	1	5	9	8	8/29/89	Oshlack	424	468	7/18/86	
	CC	4	8	1	8	4	5	0	4/4/89	Hall, et al.	264	39	10/27/86	
	CD	4	7	2	0	3	8	4	1/19/88	DiLuccio, et al.	424	78	8/21/86	
	CE	4	3	7	4	0	8	2	2/15/83	Hochschild	264	129	8/18/91	
	CF	3	8	8	0	9	9	1	04/29/75	Yolles	424	22		
	CG	4	2	6	5	8	7	5	05/05/81	Byrne, et al.	424	19		
	CH	4	2	9	2	3	0	0	09/29/81	Byrne, et al.	424	19		
	CI	4	3	4	4	4	3	1	08/17/82	Yolles	128	260		
	CJ	4	3	4	6	7	0	9	08/31/82	Schmitt	128	260		
	CK	4	4	0	6	8	8	3	09/27/83	Byrne, et al.	424	80		
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
		YES	NO											
	CL	0	5	4	4	1	4	4	06/02/93	EPO (A1)	A61K	9/20		X
	CM	0	3	5	8	1	0	5	03/14/90	EPO (A2)	A61J	3/10		X
	CN	WO	93	0	7	8	5	9	04/29/93	PCT	A61K	9/16	X	
	CO	WO	93	1	8	7	5	3	9/30/93	PCT	A61K	9/16	X	
	CP	WO	92	1	8	1	0	6	10/29/92	Japan	A61K	9/14		X
	CQ	9	3	0	0	0	6	3	01/07/93	WO (A1)	A61J	3/00		
	CR	9	3	1	0	7	6	5	06/10/93	WO (A1)	A61K	9/22		
	CS	0	0	2	1	1	2	9	09/07/88	EPO (B2)	A61K	9/16		X
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	CT	Abstract No. 2-223533 "Agent with Release-Controlled Matrix"												
EXAMINER										DATE CONSIDERED				
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	DA	4	6	2	1	1	1	4	11/04/86	Watanabe	524	451		
	DB	4	6	4	9	0	4	2	03/10/87	Davis, et al.	424	438		
	DC	4	8	0	1	4	6	0	01/31/89	Goertz, et al.	424	465		
	DD	4	8	8	0	5	8	5	11/14/89	Klimesch, et al.	264	141		
	DE	4	9	7	0	0	7	5	11/13/90	Oshlack	424	451		
	DF	4	9	9	2	1	0	0	02/12/91	Koeppf, et al.	106	125S		
	DG	5	1	0	2	6	6	8	04/07/92	Eichel, et al.	424	490		
	DH	5	3	5	0	5	8	4	09/27/94	McClelland, et al.	424	501		
	DI	5	4	5	6	9	2	3	10/10/95	Nakamichi, et al.	424	489		
	DJ	4	1	7	3	4	1	7	11/6/79	Kruder	366	89	6/20/78	
	DK	4	2	3	0	6	8	7	10/28/80	Sair et al.	424	22	5/30/78	
	DL	4	7	7	8	6	7	6	10/18/88	Yang et al.	424	79	12/20/85	
	DM	4	8	4	2	7	6	1	6/27/89	Rutherford	252	90	3/23/88	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	DN	0	2	3	9	9	8	3	11/21/91	EPO (B1)	A61J	3/06		X
	DO	0	2	7	5	8	3	4	07/27/88	EPO (A1)	A61K	9/20		
	DP	0	3	2	0	4	8	0	11/25/92	EPO (B1)	B01F	5/22		X
	DQ	0	4	3	6	7	8	6	06/08/94	EPO (B1)	B30B	11/22		X
	DR	0	4	9	1	2	3	8	03/08/95	EPO (B1)	B30B	11/22		X
	DS	2	2	0	7	3	5	5	01/23/91	Great Britain (B)	A61M	31/00		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	DT	Derwent Abstract DE 2553026 (1976)												
EXAMINER										DATE CONSIDERED				
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*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	EA	4	8	7	9	1	0	8	11/7/89	Yang et al.	424	440	10/14/88	
	EB	4	8	8	2	1	5	1	11/21/89	Yang et al.	424	440	10/14/88	
	EC	4	8	8	2	1	5	2	11/21/89	Yang et al.	424	440	10/14/88	
	ED	4	8	8	2	1	5	3	11/21/89	Yang et al.	424	440	10/13/88	
	EE	4	8	8	2	1	5	5	11/21/89	Yang et al.	424	440	10/14/88	
	EF	4	8	8	2	1	5	6	11/21/89	Yang et al.	424	440	10/14/88	
	EG	5	3	5	4	8	5	6	10/11/94	Kawashima et al.	536	127	05/23/91	
	EH	4	8	8	2	1	5	7	11/21/89	Yang et al.	424	440	10/14/88	
	EI	4	8	8	2	1	5	9	11/21/89	Yang et al.	424	440	10/14/88	
	EJ	4	9	5	9	2	0	8	9/25/90	Chakrabarti et al.	424	78	10/28/88	
	EK	5	0	3	5	5	0	9	7/30/91	Kruder	366	89	8/13/90	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	EL	0	3	5	4	3	4	5	2/14/90	EP (A2)	CO9H	9/04	Abstract	
	EM	0	3	6	8	2	4	7	5/16/90	EP (A2)	A61K	9/26		
	EN	0	3	7	5	0	6	3	6/27/90	EP (A1)	A61K	9/18		
	EO	2	2	2	3	5	3	3	9/15/90	JP (A)	A61K	47/14	Abstract	
	EP	2	2	2	3	5	1	3	9/5/90	JP (A)	A61K	9/10	Abstract	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	EQ	Derwent Abstract of JP 62040277 (1987)												
	ER	Derwent Abstract of JP58109411 (1983)												
	ES	Derwent Abstract EP 358 107 (1990)												
	ET	Sekiguchi, et al., "Studies on Absorption of Eutectic Mixture.....", Chem. Pharm. Bull., Vol. 9 (1961), pp. 866-872												
EXAMINER										DATE CONSIDERED				
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	FA	5	2	2	9	1	4	8	7/20/93	Copper	426	5	2/20/92	
	FB	5	2	4	0	4	0	0	8/31/93	Fujimoto et al.	425	310	7/27/92	
	FC	5	2	6	2	1	7	2	11/16/93	Sipos	424	490	6/19/92	
	FD	5	2	9	6	2	6	6	3/22/94	Kunugi et al.	427	213	2/19/91	
	FE	5	3	4	0	5	8	1	8/23/94	Tseng et al.	424	401	6/15/92	
	FF	5	4	7	6	5	2	8	12/19/95	Trimm et al.	71	21	12/20/93	
	FG	5	5	1	0	1	1	4	4/23/96	Borella et al.	424	452	5/2/94	
	FH	5	5	1	6	2	0	5	5/14/96	Oda et al.	366	75	1/12/95	
	FI	5	5	5	2	1	5	9	9/3/96	Mueller et al.	424	464	9/23/93	
	FJ	5	5	6	7	4	3	9	10/22/96	Myers et al.	424	486	11/4/94	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	FK	2	2	7	3	5	1	2	1/2/76	FR	A61J	3/06		X
	FL	2	2	7	3	5	8	4	1/2/76	FR	B 01 J	2/10		X
	FM	5	2	5	7	3	1	5	5/11/77	JP	A61K	9/22		X
	FN		6	6	5	0	1	0	10/14/93	EP (A1)	A61K	9/26		
	FO	1	5	0	4	5	5	3	3/22/78	GB	A61K	47/00		
	FP	8	9	7	6	0	9	1	6/18/92	AU (A)	A23L	001/09		
	FQ	9	4	2	2	4	3	1	10/13/94	WO	A61K	9/20		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	FR	A.R. Gennaro, "Particle Phenomena and Coarse Dispersions", Remington's Pharmaceutical Sciences, 17th Edition, 1985, p. 301												
	FS	J.L. Ford, "The Current Status of Solid Dispersions", Pharm. Acta Helv. 61, Nr. 3 (1986), pp. 69-88												
	FT	CA 74:67660 (1996) (1 page)												
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	GA	3	7	1	4	3	5	0	01/30/73	Gough	424	203		
	GB	5	1	6	2	1	1	7	11/10/92	Stupak, et al.	424	475		
	GC	5	1	6	5	9	5	2	11/24/92	Solomon, et al.	427	2		
	GD	5	2	3	4	6	9	7	08/10/93	Sipos	424	490		
	GE	5	0	1	3	3	0	6	05/07/91	Solomon, et al.	604	265		
	GF	5	1	6	5	9	5	2	11/24/92	Solomon, et al.	427	2		
	GG	5	4	5	1	4	2	4	11/19/95	Solomon, et al.	427	2.1		
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													YES	NO
	GH	9	3	2	4	1	1	0	12/9/93	WO	A61K	9/20	X	
	GI	2	4	3	9	5	3	8	03/04/76	DE	A61K	9/22	Abstract	
	GJ	2	0	4	5	9	6		12/10/86	EP	A61K	9/14	Abstract	
	GK	5	8	0	8	6	0		02/94	EP (A1)				
	GL	0	2	4	0	9	0	4	10/14/87	EPO	A61K	9/20	abstract	
	GM	0	5	2	9	3	9	6	03/03/93	EPO	A61K	9/20	abstract	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	GN	CA 101:60081 (1996) (1 page)												
	GO	CA 113:98975 (1996) (1 page)												
	GP	CA 113:218240 (1996) (1 page)												
	GQ	CA 114:30199 (1996) (1 page)												
	GR	CA 112:75438 (1996) (1 page)												
	GS	CA 115:177364 (1997) (1 page)												
	GT	R. Kinget, et al., "Preparation and Properties of Granulates Containing Solid Dispersions", Acta Phar. Tech., Vol. 31, No. 2, 1985, pp. 57-62												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Benjamin OSHLACK et al.								
						FILING DATE: Herewith		GROUP: Unknown						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	HA	2	7	3	8	3	0	3	3/13/56	Blythe, et al.	167	82		
	HB	3	0	6	5	1	4	3	11/20/62	Christenson, et al.				
	HC	3	6	5	2	5	8	9	3/28/72	Flick, et al.	260	326.5M		
	HD	3	8	3	0	9	3	4	8/20/74	Flick, et al.	424	330		
	HE	3	8	4	5	7	7	0	11/5/74	Theeuwes, et al.	128	260		
	HF	3	9	5	0	5	0	8	4/13/76	Mony, et al.	424	19		
	HG	3	9	6	5	2	5	6	6/22/76	Leslie	424	22		
	HH	3	9	7	4	1	5	7	8/10/76	Shetty, et al.	260	247.2B		
	HI	4	0	1	3	7	8	4	3/22/77	Speiser	424	19		
	HJ	4	0	7	6	7	9	8	2/28/78	Casey et al.	424	419		
	HK	4	2	5	9	3	1	4	3/31/81	Lowey	424	19		
	HL	4	3	1	0	4	8	3	1/12/82	Dorfel, et al.	264	117		
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	HM	9	1	1	9	4	8	4	12/26/91	PCT	A61K	9/16	Abstract	
	HN	9	1	1	9	4	8	5	12/26/91	PCT	A61K	9/16	Abstract	
	HO	9	2	0	1	4	4	6	2/6/92	PCT	A61K	9/50		
	HP	9	2	0	2	2	0	9	2/20/92	PCT	A61K	9/22	Abstract	
	HQ	9	2	0	5	7	7	4	4/16/92	PCT	A61K	9/18	Abstract	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	HR	M.J. Jozwiakowski et al., "Characterization of a Hot-Melt Fluid Bed Coating Process for Fine Granules", Pharm. Research, Vol. 7, No. 11, 1990, pp. 1119-24												
	HS	B. Evrard et al., "Melt Granulation With a New Laboratory High-Shear Mixer", Laboratoire de Pharmacie Galenique, Institut de Pharmacie												
	HT	M. Niskanen et al., "Pelletization in a Centrifugal Granulator, Part I: Effects of Binder-Solution Concentration", Pharm. Tech. Int'l., October 1990, pp. 22-38												
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						FILING DATE: Herewith		GROUP: Unknown										
U.S. PATENT DOCUMENTS																		
*EXAMINER INITIAL	IA	IB	IC	ID	IE	IF	IG	IH	II	IJ	IK	IL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
													4 3 4 3 7 8 9	8/10/82	Kawata, et al.	424	461	
													4 3 6 6 1 7 2	12/28/82	Lednicer	424	330	
													4 3 8 0 5 3 4	4/19/83	Fukui, et al.	264	38	
													4 3 8 9 3 9 3	6/21/83	Schor, et al.	424	19	
													4 4 2 1 7 3 6	12/20/83	Walters, et al.	424	21	
													4 4 8 3 8 4 7	11/20/84	Augart	424	22	
													4 6 1 3 6 1 9	9/23/86	Sleigh et al.	514	546	
													4 8 0 1 4 5 8	1/31/89	Hidaka, et al.	424	443	
													4 8 3 4 9 8 4	5/30/89	Goldie, et al.	424	488	
													4 8 4 4 9 0 7	7/4/89	Elger et al.	424	465	
													4 8 4 4 9 0 9	7/4/89	Goldie et al.	424	480	
													4 9 1 7 8 9 9	4/17/90	Geoghegan et al.	424	19	
FOREIGN PATENT DOCUMENTS																		
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION					
													YES	NO				
		IM	9	2	0	6	6	7	9	4/30/92	PCT	A61K	9/16					
		IN	9	2	2	2	2	8	3	12/23/92	PCT	A61K	9/02					
		IO	9	3	0	0	0	7	6	1/7/93	PCT	A61K	9/51					
		IP	9	3	0	4	6	7	5	3/18/93	PCT	A61K	31/16					
		IQ	9	3	0	7	8	6	1	4/29/93	PCT	A61K	9/50					
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)																		
	IR	L. Lachman et al., "The Theory and Practice of Industrial Pharmacy", p. 315, Lea & Febiger, Phi. 1976.																
	IS	FDA Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation, January 1994																
	IT	T. Schaefer et al., "Melt Pelletization in a High Shear Mixer I Effects of Process Variables and Binder", Acta Pharm. Nord. Vol. 4, No. 3, pp. 133-140, 1992.																
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										FILING DATE: Herewith		GROUP: Unknown			
U.S. PATENT DOCUMENTS															
*EXAMINER INITIAL		DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	JA	4	9	2	5	6	7	5	5/15/90	Giannini, et al.	424	78			
	JB	4	9	3	5	2	4	6	6/19/90	Ahrens	424	490			
	JC	4	9	6	7	4	8	6	11/6/90	Doelling	34	1			
	JD	4	9	7	0	0	7	5	11/13/90	Oshlack	424	451			
	JE	4	9	8	7	1	3	6	1/22/91	Kreek et al.	514				
	JF	4	9	9	0	3	4	1	2/5/91	Goldie et al.	424	484			
	JG	5	0	0	7	7	9	0	4/16/91	Shell	424	451			
	JH	5	0	2	6	5	6	0	6/25/91	Makino, et al.	424	494			
	JI	5	0	3	0	4	0	0	7/9/91	Danielson, et al.	264	101			
	JJ	5	1	2	6	1	4	5	6/30/92	Evenstad	424	465			
	JK	5	1	3	2	1	4	2	7/21/97	Jones, et al.	427	196			
	JL	5	1	6	7	9	6	4	12/1/92	Muhammed, et al.	424	482			
FOREIGN PATENT DOCUMENTS															
		DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO	
	JM	9	3	1	7	6	6	7	9/16/93	PCT	A61K	9/16	X		
	JN	9	4	0	3	1	6	0	2/17/94	PCT	A61K	9/32			
	JO	9	4	0	3	1	6	1	2/17/94	PCT	A61K	9/52			
	JP	9	4	0	5	2	6	2	3/17/94	PCT	A61K	9/16			
	JQ	9	4	2	3	7	0	0	10/27/94	PCT	A61K	9/16			
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
	JR	T. Schaefer et al., "Melt Pelletization in a High Shear Mixer II Power Consumption and Granule Growth", Acta Pharm. Nord. Vol. 4, No. 3, pp. 141-148, 1992													
	JS	T. Schaefer, et al., "Melt Granulation in a Laboratory Scale High Shear Mixer", Drug Dev. and Indust. Phar., Vol. 16, No. 8, pp. 1249-1277, 1990.													
	JT	McTaggart, C.M. et al., "The Evaluation of Formulation and Processing Conditions of a Melt Granulation Process", Int'L. J. Pharm. Vol. 19, No. 2, issued 1984, pp. 139-148													
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				FILING DATE: Herewith		GROUP: Unknown								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	KA	5	1	6	9	6	4	5	12/8/92	Shukla, et al.	424	499		
	KB	5	1	7	8	8	6	8	1/12/93	Malmqvist-Granlund et al.	424	490		
	KC	5	1	9	6	2	0	3	3/23/93	Boehm	424	490		
	KD	5	2	0	4	1	1	9	4/20/93	Shiobara, et al.	424	489		
	KE	5	2	6	6	3	3	1	11/30/93	Oshlack, et al.	424	468		
	KF	5	2	9	2	4	6	1	3/8/94	Juch et al.	264	37		
	KG	5	3	0	0	3	0	0	4/5/94	Egidio, et al.	424	456		
	KH	5	3	9	5	6	2	6	3/7/95	Kotwal, et al.	424	472		
	KI	5	4	0	3	5	9	3	4/4/95	Royce	424	489		
	KJ	5	4	4	3	8	4	6	8/22/95	Yoshioka et al.	424	498		
	KK	5	4	5	3	2	8	3	9/26/95	Munch et al.	424	489		
	KL	5	4	7	2	7	1	0	12/5/95	Klokkers-Bethke, et al.	424	468		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	KM	9	5	1	4	4	6	0	6/1/95	PCT	A61K	9/14		
	KN	0	0	3	2	0	0	4	12/80	EP (A)	A61K	9/22		
	KO	0	0	4	3	2	5	4	5/30/84	EP (B1)	A61K	9/26		
	KP	0	0	6	8	4	5	0	1/1/90	EP (B1)	A61K	9/20		
	KQ	0	0	9	7	5	2	3	8/83	EP (A2)	A61K	9/26		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	KR	El-Shanawany, S., "Sustained Release of Nitrofurantion From Inert Wax Matrixes", J. Controlled Release, Vol. 26, No. 1, issued 1993, pp. 11-19												
	KS	P. Flanders, et al., "The Control of Drug Releases From Conventional Melt Granulation Matrices", Drug Dev. and Industrial Pharm., Vol. 13, No. 6, pp. 1001-22, 1987.												
	KT	Thomsen, L. Juul, "Matrix Pellets Prolonged Formulations Prepared by Melt Pelletization", Dept. of Pharm. Royal Danish School of Pharmacy, 1992												
EXAMINER										DATE CONSIDERED				
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						FILING DATE: Herewith		GROUP: Unknown							
U.S. PATENT DOCUMENTS															
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	LA	5	2	7	1	9	3	4	12/2/93	Goldberg, et al.	424	401			
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
														YES	NO
	LB	0	1	0	8	2	1	8	5/16/84	EP (A2)	A61K	9/22			
	LC	0	1	4	7	7	8	0	12/84	EP (A2)	A61K	9/32			
	LD	0	1	5	2	3	7	9	8/21/85	EP (A2)	A61K	9/50			X
	LE	0	1	8	9	8	6	1	8/6/86	EP (A2)	A61K	47/00			
	LF	0	2	0	5	2	8	2	9/95	EP (B1)	A61K	9/22			
	LG	0	2	1	4	7	3	5	7/86	EP (A2)	A61K	9/22			
	LH	0	2	4	1	6	1	5	9/18/91	EP (B1)	A61K	9/22			
	LI	0	2	4	8	5	4	8	5/87	EP (A2)	A61K	9/22			
	LJ	0	2	4	9	3	4	7	5/87	EP (A2)	A61K	31/485			
	LK	0	2	4	9	3	4	7	6/29/94	EP (B1)	A61K	31/485			
	LL	0	2	5	1	4	5	9	5/87	EP (A2)	A61K	9/22			
	LM	0	2	5	3	1	0	4	6/87	EP (A1)	A61K	9/00			
	LN	0	2	5	4	9	7	8	2/3/88	EP (A1)	A61K	9/22			
	LO	0	2	5	6	1	2	7	2/24/88	EP (B1)	C12N	9/00			
	LP	0	2	6	7	7	0	2	5/18/88	EP (A2)	A61K	9/14			
	LQ	0	2	7	1	1	9	3	6/15/88	EP (A2)	A61K	31/485			
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)															
	LR	Thomsen, L. Juul, et al., "Prolonged Release Matrix Pellets Prepared by Melt Pelletization I. Process Variables", Drug Development and Industrial Pharmacy, Vol. 19, No. 15, pp. 1867-1887 (1993)													
	LS	Thomsen, L. Juul, et al., "Prolonged Release Matrix Pellets Prepared by Melt Pelletization II. Hydrophobic Substances as Melttable Binders", Drug Development and Industrial Pharmacy, Vol. 20, No. 7, pp. 1179-1197 (1994)													
	LT	Thomsen, L. Juul, "Utilizing melt pelletization technique for the preparation of prolonged release products", Pelletization, (material elaborated by assistant Prof. Lars Juul Thomsen, Dept. of Pharmaceutics, Royal Danish School of Pharmacy for the DIE course "Pelletization Technology", November 1992, 106 pages plus appendixes													
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				FILING DATE: Herewith		GROUP: Unknown								
U.S. PATENT DOCUMENTS														
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		5	4	7	8	5	7	7	12/16/95	Sackler et al.	424			
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		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
		0	2	9	5	2	1	2	12/14/88	EP (A2)	A61K	47/00		
	MC	0	2	9	8	3	5	5	11/14/90	EP (B1)	A61K	9/50		X
	MD	0	3	0	0	8	9	7	7/88	EP (A2)	A61K	9/22		X
	ME	0	3	2	7	2	9	5	8/9/89	EP (A2)	A61K	9/52		
	MF	0	3	5	1	5	8	0	1/24/90	EP (A2)	A61K	9/22		
	MG	0	3	6	1	6	8	0	4/4/90	EP (B1)	A61K	9/46		
	MH	0	3	6	1	9	1	0	4/4/90	EP (A1)	A61K	9/16		
	MI	0	3	7	7	5	1	7	7/11/90	EP (A2)	A61K	31/52		
	MJ	0	3	7	7	5	1	8	1/90	EP (A2)	A61K	9/52		
	MK	0	4	1	5	6	9	3	3/6/91	EP (A1)	A61K	37/02		
	ML	0	4	3	0	2	8	7	6/5/91	EP (B1)	A61K	9/54		
	MM	0	4	5	2	1	4	5	10/16/91	EP (A2)	A61K	9/14		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	MN	Thomsen, L. Juul, "Prolonged Release Matrix Pellets Prepared by Melt Pelletization. Part IV: Drug Content, Drug Particle Size and Binder Composition", Pharmaceutical Technology Europa, pp. 19-22 (October 1994)												
	MO	N. Follonier et al., "Evaluation of Hot-Melt Extrusion as a New Technique for the Production of Polymer-Based Pellets for Sustained Release Capsules Containing High Loadings of Freely Soluble Drugs", Drug. Dev. and Industr. Pharm., Vol. 20, No. 8, pp. 1323-1339, (1994)												
	MP	Sustained Release Medications, pp. 50-53, Noyes Data Corp. (J.C. Johnson), 1980.												
	MQ	M.A. Longer, "Sustained-Release Drug Deliver Systems", Remington's Pharm. Sci., 18th Edition, pp. 1676-1693, 1990.												
	MR	M. Zahirul I. Khan, "Recent Trends and Progress in Sustained or Controlled Oral Delivery of Some Water Soluble Drugs: Morphine Salts, Diltiazem and Captopril", Drug Devl. and Industr. Pharm., Vol. 21, No. 9, pp. 1037-1070, 1995.												
	MS	J.P. Skelly, "Scale-up of Immediate Release Oral Solid Dosage Forms, AAPS/FDA Workshop Committee, Pharmaceutical Technology, pp. 68-74, April 1995.												
	MT	SK Baveja et al., Int. J. Pharmaceutics, 41, (1988), pp. 55-62.												
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U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	NA	DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
		5	3	7	8	4	6	2	01/95	Boedecker, et al.	424	94.29		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
													YES	NO
	NB	0	4	6	5	3	3	8	01/08/92	EPO	A61K	9/16	No	
	NC	0	6	2	4	3	6	6	04/29/94	EPO	A61K	31/135		
	ND			5	7	2	2	4	5/7/86	Australia	A61K	47/00		
	NE	0	4	6	3	8	3	3	6/91	EP (A2)	A61K	9/26		
	NF	0	5	2	6	8	6	2	2/10/93	EP (A1)	A61K	9/20		
	NG	0	5	3	1	6	1	1	4/92	EP (A1)	A61K	9/02		
	NH	0	5	3	3	2	9	7	3/24/93	EP (A1)	A61K	9/46		
	NI	0	5	3	4	6	2	8	3/31/93	EP (A1)	A61K	31/485		
	NJ	0	5	3	5	8	4	1	9/92	EP (A1)	A61K	31/485		
	NK	0	5	4	6	6	7	6	6/16/93	EP (A1)	A61K	31/60		
	NL	0	5	8	2	3	8	0	2/9/94	EP (A1)	B01J	2/16		
	NM	0	5	9	5	3	1	1	5/4/94	EP (A1)	A61K	31/44	No	
	NN	0	6	0	9	9	6	1	8/10/95	EP (A1)	A61K	31/485		
	NO	0	6	2	4	3	6	6	5/29/96	EP (B1)	A61K	31/135		
	NP	0	6	3	6	3	7	0	2/1/95	EP (A1)	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	NQ	Formulating for Controlled Release with METHOCEL® Premium Cellulose Ethers, The Dow Chemical Company, 1989.												
	NR	M.S. Vazquez et al., Ddrug Dev. & Ind. Pharmacy, 18 (11 & 12), pp. 1355-1378 (1992).												
	NS	L W S Cheong et al., Pharm. Res. 9 (11), pp. 1510-1514 (1992).												
	NT	Hunt et al., Clin. Ther., Vol. 13, No. 4, pp. 482-488, 1990												
EXAMINER									DATE CONSIDERED					
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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Benjamin OSHLACK et al.								
						FILING DATE: Herewith		GROUP: Unknown						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	OA	5	7	0	0	4	1	0	12/23/97	Nakamichi et al	264	122		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	OB	0	6	4	2	7	8	8	3/95	EP (A2)	A61K	31/135		
	OC	0	9	9	7	3	9	9	4/1/64	GB				
	OD	1	4	0	5	0	8	8	6/3/71	GB	A61K	9/26		
	OE	1	5	1	3	1	6	6	6/7/78	GB	B29B	1/02		
	OF	2	0	3	0	8	6	1	4/16/80	UK (A)	A61J	3/08		
	OG	2	0	5	3	6	8	1	4/4/84	GB(B)	A61K	9/22		
	OH	2	1	1	1	3	8	6	12/82	GB (A)	A61K	9/20		
	OI	2	1	1	7	2	3	9	3/83	GB (A)	A61K	9/20		
	OJ	2	1	3	1	3	5	0	3/4/95	Canada (A1)	A61K	31/135		
	OK	2	1	9	6	8	4	8	5/88	GB (A)	A61K	9/22		
	OL	2	2	4	6	5	1	4	2/5/92	GB (A)	A61K	9/16		
	OM	2	2	8	1	2	0	4	3/1/95	GB (A)	A61K	9/16		
	ON	2	2	8	4	7	6	0	6/21/95	UK (A)	A61K	9/16		
	OO	2	6	4	2	4	2	0	3/90	FR (A1)	C07C	55/10		
	OP	3	6	0	2	3	6	0	7/30/87	DE (A1)	B65G	65/06		X
	OQ	3	6	0	2	3	7	0	8/6/87	DE (A1)	A61K	45/06		X
	OR	3	6	2	3	1	9	3	1/14/88	DE (A1)	A61K	31/205		X
	OS	4	3	2	9	7	9	4	3/9/95	DE (A1)	A61K	31/135		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	OT	METHOCEL, Colorcon. Technical Information												
EXAMINER										DATE CONSIDERED				
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FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION				
										YES	NO			
	PB	0	0	2	1	1	2	9	9/7/88	EP (B2)	A61K	9/16		
	PC	0	3	3	8	3	8	3	3/24/93	EPO (B1)	A61K	9/54		X
	PD	2	0	8	2	5	7	3	5/24/93	CA	A61K	047/38		
	PE	2	1	5	0	3	0	4	12/1/95	CA (A1)	B01J	2/20		
	PF	2	2	8	1	2	0	4	3/1/95	GB (A)	A61K	9/16		
	PG	2	2	8	4	7	6	0	6/21/95	GB (A)	161K	9/16		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	PH	DA Alderman, Int. J. Pharm. Tech. and Prod. Mfr., 5(3), pp. 1-9, 1984.												
	PI	HE Huber et al., J. Pharm. Sci. 55 (9), Sept. 1966, pp. 974-976.												
	PJ	Lin SY et al., Current Therapeutic Research 52 (3), pp. 486-492, Sept., 1992.												
	PK	Aqualon Technical Information Bulletin, VC-585, 1991												
	PL	P. Colombo, Advanced Drug Delivery Reviews, 11 (1993), pp. 37-57.												
	PM	KV Ranga Rao et al., Int. J. Pharmaceutics, 48 (1988), pp. 1-13.												
	PN	JE Hogan, Drug Dev. & Ind. Pharmacy, 15 (6 & 7), p. 975-999, (1989)												
	PO	JL Ford et al., Int. J. Pharmaceutics, 24 (1985), pp. 327-338.												
	PP	PB Daly et al., Int. J. Pharmaceutics, 18 (1984), pp. 201-205.												
	PQ	E.M.G. van Bommel, "Production and Evaluation of In Vitro Release Characteristics of Spherical Gradient Matrix Systems", Acta Phar., Technol. 3b (2), pp. 74-78, 1990.												
	PR	Nicolas Follonier et al., "Various Ways of Modulating the Release of Diltiazem Hydrochloride from Hot-melt Extruded Sustained Release Pellets Prepared Using Polymeric Materials", Journal of Controlled Release, 36, pp. 243-250 (1995).												
	PS	Alan Royce et al., "Alternative Granulation Technique: Melt Granulation", Drug Development and Industrial Pharmacy, 22 (9 & 10), pp. 917-92 (1996).												
	PT	Derwent Abstract of EP 0208144, published 1-14-87												
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	QA													
	QB													
	QC													
	QD													
	QE													
	QF													
	QG													
	QH													
	QI													
	QJ													
	QK													
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	QL	EP	02	0	4	5	9	6	12/10/86	EPO(A1)	A61K	9/16		
	QM	EP	02	0	8	1	4	4	1/14/87	EPO(A1)	A61K	9/16		
	QN	EP	06	6	7	0	6	5	8/25/93	EPO(A1)	A61K	9/16		
	QO	9	1	0	4	0	1	5	4/4/91	WO	A61K	9/16		
	QP													
	QQ													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	QR													
	QS													
	QT													
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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Benjamin OSHLACK, et al.										
				FILING DATE: Herewith		GROUP: Unknown								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	RA													
	RB													
	RC													
	RD													
	RE													
	RF													
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
												YES	NO	
	RG	0	5	7	4	8	9	4	12/22/93	EPO (A1)	A61K	31/575		
	RH													
	RI													
	RJ													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	RK	English translation of Japanese text of J.L. White, Twin Screw Extrusion, Technology and Principles, pages 14 and 37, 1981.												
	RL													
	RM													
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